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Allie Barrett

PATENT

Applicant: Van Tassel, et al.
Serial No.: 09/382,275
Filed: August 25, 1999
Title: **IMPLANTABLE DEVICE FOR PROMOTING REPAIR OF A BODY LUMEN**
Examiner: Hieu Phan
Group Art Unit: 3738
Atty. Docket No. : 20220-311

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

REPLY BRIEF UNDER 37 CFR § 41.41

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Please consider the following remarks in response to the Examiner's Answer dated November 3, 2005 in connection with the above-referenced application.

I. Burden on the Examiner

The application as filed must be presumed adequate until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. See, e.g., *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). The Examiner's Answer further demonstrates that no sufficient evidence or reasoning exists

I. Unrebutted Argument

Perhaps the strongest evidence submitted in its Appeal Brief in support of Applicants' position is found at page 18, lines 1-4 of the originally filed application where it is stated:

> Stent 14 is preferably a balloon expandable device made of expandable metal or braided wire, but also may be designed as a self-expanding structure. *It may also be fabricated from a composition of metallic fibers, **uniformly** laid to form a three dimensional, non-woven structure, such as is shown in Figure 2.* (emphasis added).

This text shows a direct distinction between a stent 14 "made of expandable metal or braided wire", ***which is precisely what is disclosed in Figure 1*** to a "composition of metallic fibers, uniformly laid to form a three dimensional, non-woven structure ***such as is shown in Figure 2***." (emphasis added). The distinction is especially pronounced in the context of the immediately preceding paragraph on Page 17, lines 24-30 which specifically correlates the stent 14 of the above paragraph to Figure 1. Yet the Examiner does not even discuss this text in the Examiner's Answer. This evidence favoring Applicants' position is therefore completely unrebutted. On this basis alone the rejection should thus be reversed.

II. Conclusory Arguments

With reference to the text at Page 15, lines 8-15 of the originally filed application, the Examiner states that this text "only provides support for microholes and does not support the limitation of 'substantially free of holes larger than said microholes'". Yet there is no elaboration on this statement.

The Examiner's statement ignores that this text describes a stent formed of "metallic fibers **uniformly** laid to form a three-dimensional **non-woven matrix**" (emphasis added). If these terms do not support the "substantially free of holes larger than said microholes" terminology, then the Examiner is required to explain why this is the case. The Examiner cannot overcome the presumption that the application is adequate by merely making a conclusory statement as done in the Examiner's Answer.

Indeed, the terms "uniformly" and "non-woven matrix" precisely do support the "substantially free of holes larger than said microholes" terminology based on the plain meaning of the terms themselves. Metallic fibers that are "uniformly laid" to form a "non-woven matrix" are metallic fibers that are distributed without interruptions along that matrix, i.e., the fibers are **uniformly** distributed. In other words, a matrix with a large hole (e.g. larger than a microhole) along its surface would mean the fibers of the matrix are no longer **uniformly laid**. And since the matrix in the present application exhibits porosity due to the presence of microholes (described at length in the present application), the only way the non-woven matrix can be both (1) made of metallic fibers **uniformly laid** and (2) still have porosity, is for that matrix to be "substantially free of holes larger than said microholes", precisely as claimed.

The plain meaning of these terms is even more evident when one considers the preferred matrix materials cited in the very same paragraph of the above-mentioned text as having these very properties, namely, the BEKIPOR® filter medium manufactured by the Bekaeart Corporation of Marrietta, GA that is cited on Page 15, lines 15-18 of the application. One of ordinary skill in the art would be well aware that this BEKIPOR filter medium is "substantially free of holes larger than said microholes" by the well known composition of the BEKIPOR filter medium.

In this regard, at the request of the Board, Applicant can provide descriptive materials showing the BEKIPOR filter medium confirming that this filter medium is composed of "metallic fibers uniformly laid to form a three-dimensional non-woven matrix" and is "substantially free of holes larger than said microholes". Alternatively, the Board may take judicial notice of this information at www.bekaert.com.[1] In any event, one of ordinary skill reading the reference to the BEKIPOR filter medium would be very well apprised of the "substantially free of holes larger than said microholes" nature of the invention. Thus, any room for doubt as to the meaning of this text is removed and

[1] First click on "Products"; then click on "Porous and Filter Media"; then click on "Bekipor® Porous Media".

cannot be properly contradicted, least of which by a mere conclusory statement by the Examiner.

III. Figures 1 and 2 Show Two Different Stent Materials

The Examiner continues to equate Figure 2 as merely showing "part of what a stent, such as a strut of a stent (14) in figure 1, my [sic, might]) look like when it is enlarged". Yet, the Examiner fails to address the arguments made in the Applicants' Appeal Brief showing in the text where the stent of Figure 1 is distinguished from the stent of Figure 2. These arguments are amplified in the above Section I of this Reply Brief. The Board is also again referred to Page 10, lines 12-13 where Figure 2 is described as showing a "preferred material" (e.g., the BEKIPOR® filter material) from which a stent "like that shown in Figure 1" could be replaced. The Examiner is completely silent as to these arguments.

IV. The Written Description Standard

Although not stated specifically in the Examiner's Answer, it seems that the Examiner would only be willing to withdraw the rejection if the exact phrase "substantially free of holes larger than said microholes" is found within the specification of the originally filed application. In this regard, it is noted that this is not the standard required in order to satisfy 35 U.S.C. Section 112, first paragraph. A claimed invention need not be described *ipsis verbis* in the specification in order to satisfy the disclosure requirements of 35 U.S.C. Section 112. *Ex parte Holt*, 10 USPQ2d 1211 (Bd Pat App & Inter, 1991). Hence, to the extent the Examiner ascribes to a higher standard as appears to be the case, the Examiner's position should be rejected.

V. Conclusion

For at least all the reasons stated herein, it is submitted that the Examiner's rejection is erroneous. As demonstrated both in Applicant's Appeal Brief and in this Reply Brief, the Examiner has failed to provide sufficient evidence or reasoning to rebut the presumption and that the specification provides adequate written description under 35 U.S.C. Section 112, first paragraph, for all pending claims. As a result, the

Applicant's seek a reversal of the Examiner's rejection on this appeal. Reversal is hereby affirmatively requested.

To our knowledge, there are no further Appeal Brief fees due, however, the Commissioner is hereby authorized to charge payment of any additional fees or credit any overpayment to Deposit Account No. 50-2809.

Respectfully submitted,

Dated: JAN. 3, 2006

James W. Inskeep, Esq.
Registration No. 33,910

INSKEEP INTELLECTUAL PROPERTY GROUP, INC.
2281 W. 190th St., Suite 200
Torrance, CA 90504
Telephone: (310) 755-7800
Facsimile: (310) 327-3466